OCT - 9 2003

K032854

Section A. 510(k) Summary

Submitter: Unomedical A/S Infusion Devices, Aaholmvej 1-3, Osted, DK-4000 Roskilde, Denmark

Unomedical Contact: Rabi Gharabli, Quality Assurance Manager, Unomedical A/S Infusion Devices, Telephone: + 45 46 42 78 60, Fax + 45 46 42 78 15

Name of Device: Unomedical Monica Infusion Set

Predicate Devices:

- Maersk Medical Quick Set Infusion Set "approved under the name Contour Infusion Set", 510K number K991759
- Maersk Medical Paradigm Quick Set Infusion set , 510K number K011071
- Maersk Medical Pureline Comfort Subcutaneous Infusion Set, 510K number K972135
- MiniMed Quick-Serter Infusion Set Insertion System, 510K number K992300

Description of the Modified Device: The Unomedical Monica Set is an infusion administration set, connecting to a reservoir/infusion pump and inserted in the subcutaneous tissue of a user.

The administration set attaches to the reservoir by means of a "tubing connector", and subcutaneously in to the user through an indwelling catheter made of polytetrafluoroethylene (PTFE). The tubing is made of two layers: the inner layer is polyethylene; the outer is polyurethane. The indwelling catheter is introduced into the subcutaneous tissue by a removable 27 gauge introducer needle (cannula) made of AISI 304 stainless steel.

Intended Use of the Modified Device: The Unomedical Monica Infusion Set is intended for the subcutaneous infusion of medication, including insulin from an external pump. The infusion set is neither intended nor indicated for use with blood or blood products.

Comparison of the Technological Features of the Modified Device and Predicate Devices:
The Unomedical Monica Infusion Set is substantially similar to the Infusion Sets listed abovunder Predicate Devices (lawfully marketed predicate device). The sets are intended for subcutaneous delivery of insulin or other appropriately labelled medicines from an infusion pump to a pump user. The sets attach proximally to a reservoir by means of a tubing connector, and insert distally into the device user's subcutaneous tissues with a removable stainless steel needle and flexible cannula.

Signed,

John M. Lindskog 9/9-2003
John M. Lindskog Date
General Manager
Unomedical A/S
Infusion Devices

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. John M. Lindskog
General Manager
Unomedical A/S
Business Unit Infection Devices
Åholmvej 1-3, Osted
4000 Roskilde,
DENMARK

Re: K032854
Trade/Device Name: Unomedical Monica Infection Set
Regulation Number: 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: September 8, 2003
Received: September 15, 2003

Dear Mr. Lindskog

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K032854

Device Name: Unomedical Monica Infusion Set

Indications for Use: Unomedical Monica Infusion Sets are indicated for the subcutaneous infusion of medication from an external pump.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Patricia Cucuzzella

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K032854

Prescription Use ✓ **or** **Over-the-Counter Use** _____
(Per 21 CFR 801.109)